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| APPLICATION NO.                        | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-----------------|----------------------|-------------------------|------------------|
| 10/627,427                             | 07/25/2003      | David W. Plank       | 6273US                  | 2338             |
| 30173                                  | 7590 11/08/2004 |                      | EXAMINER                |                  |
| GENERAL MILLS, INC.                    |                 |                      | PADEN, CAROLYN A        |                  |
| P.O. BOX 1113<br>MINNEAPOLIS, MN 55440 |                 |                      | ART UNIT                | PAPER NUMBER     |
|  |                 |                      | 1761                    |                  |
|  |                 |                      | DATE MAILED: 11/08/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary  |   | Application No.  | Applicant(s)                                     |  |  |  |
|--|---|--|--|--|--|--|
|  |   | 10/627,427   | PLANK ET AL.                                     |  |  |  |
|  |   | Examiner   | Art Unit   |  |  |  |
|  |   | Carolyn A Paden  | 1761   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |  |  |  |  |  |
| Status   | •   |  |  |  |  |  |
| 1) 🛛   | Responsive to communication(s) filed on 21  | February 2004.   |  |  |  |  |
|  |   |  |  |  |  |  |
| 3)   | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |
| Dispositi  | on of Claims  |  |  |  |  |  |
| 4) ⊠ Claim(s) 1-29 is/are pending in the application. 4a) Of the above claim(s) 23-26 is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-10, 13-16, 18-20,22, 27-29 is/are rejected.  7) ⊠ Claim(s) 11,12,17 and 21 is/are objected to.  8) □ Claim(s) are subject to restriction and/or election requirement.   |   |  |  |  |  |  |
| Application  | on Papers   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |
| Priority u   | nder 35 U.S.C. § 119  |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |  |  |  |  |  |
| 2) 🔲 Notice  | (s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 No(s)/Mail Date 6-3!-01) 10-29-03 | 4) Interview Summary Paper No(s)/Mail Da  5) Notice of Informal P  6) Other: | (PTO-413)<br>ate<br>ratent Application (PTO-152) |  |  |  |

## **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22 and 27-29, drawn to a fat or food containing reduced trans fat levels and a method of making a food with these reduced trans fat levels, classified in class 426, subclass 601.
- II. Claims 23-26, drawn to a method of communicating a beneficial effect of a food, classified in class 705, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Hornilla on November 2, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22 & 27-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-3, 6-10, 13-16, 18-20, 22 & 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qi in view of Baileys.

Qi discloses dry edible oil and starch composition containing omega fatty acids and up to 15% cyclodextrin (see abstract). At column 5, lines 31-50, the manufacture of cyclodextrin, using the enzyme of claim 2 is described. The use of the omega fatty acids in the composition to lower cholesterol is described at column 1, lines 15-26. Lecithin is used in the product and is a known emulsifier. Corn syrup solids are also employed and these corn syrup solids would likely act to hydrate the cyclodextrin. The oil in the product may derive from any of a number of sources that include a grain or plant source (column 3, lines 22-30). The claims appear to differ from Qi in the recitation of the use of a reduced trans fat. Swern is relied upon for evidence that natural fats, like the fats in Qi, do not contain trans fats. Thus it would have been obvious to one of ordinary skill in the art to expect that the fat of Qi provided a source of low trans fat to the Qi emulsion.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qi in view of Swern as applied to claims 1-3, 6-10, 13-16, 18-20, 22 & 27-29 above, and further in view of Takada.

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The claims appear to differ from Qi in the recitation of the source of the enzyme. The source of the enzyme-creating ingredients does not carry any weight in the present claimed invention. But Takada also teaches that the desired gene coated enzymes are very well known in the art. To use a cyclodextrin glucanotransferase from a gene coated source would have been an obvious way to keep a consistent source of cyclodextrin on hand for use in food manufacture.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roderbourg in view of Swern.

Roderbourg discloses reducing the cholesterol in animal fat by complexing the fat with any of the varieties of cyclodextrin in the amount set forth in the claim (column 3, lines 25-45). The claim appears to differ in the suggestion that the fat is trans free. Swern is relied upon to show that natural fats are well known to be a good source of trans free fat. Thus it would have been obvious to one having ordinary skill in the art to expect that the cyclodextrin and composition of Roderbourg would have all of the desired characteristics of claim 1.

Claims 1-10, 13-16, 18-20, 22-24, 27-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting

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as being unpatentable over claims 1-20 of copending Application No. 10/318,445, now PgPub 2004/0116382 in view of Swern.

Plank discloses food products that contain cyclodextrins and have a beneficial hypocholesterolemic effect. Claim 1 in the PgPub shows the amount of cyclodextrin in the composition. Cyclodextrin glycosyl transferase is shown in claim 2. Beta and gamma cyclodextrin are set forth in claims 3 and 5. No unobvious or unexpected results are seen from gene coding the fat to contain cyclodextrin. The cyclodextrin is hydrated by the water that is in the ingredient list. The range of foods using cyclodextrin is shown at paragraphs 37 and 62. The claims appear to differ in the recitation of the reduced trans level. Swern is relied upon for evidence that natural fats, like the fats in Plank, do not contain trans fats. Thus it would have been obvious to one of ordinary skill in the art to expect that the fat of Plank provided a source of low trans fat to the Plank foods.

This is a <u>provisional</u> obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13-16, 18-20,22-24,27-29 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/318,445 which has a common inventor with the instant application in view of Swern. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Plank discloses food products that contain cyclodextrins and have a beneficial hypocholesterolemic effect. Claim 1 in the PgPub shows the amount of cyclodextrin in the composition. Cyclodextrin glycosyl transferase is shown in claim 2. Beta and gamma cyclodextrin are set forth in claims 3 and 5. No unobvious or unexpected results are seen from gene

coding the fat to contain cyclodextrin. The cyclodextrin is hydrated by the water that is in the ingredient list. The range of foods using cyclodextrin is shown at paragraphs 37 and 62. The claims appear to differ in the recitation of the reduced trans level. Swern is relied upon for evidence that natural fats, like the fats in Plank, do not contain trans fats. Thus it would have been obvious to one of ordinary skill in the art to expect that the fat of Plank provided a source of low trans fat to the Plank foods.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8, 10, 13-16, 18, 22 & 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito (JPO S62-11072 provided patent with translation) as further evidenced by Swern.

Saito discloses a fat-reducing food containing cyclodextrin (any of three isoforms) and gamma linolenic acid. The concept of using this composition for modulating cholesterol levels and blood pressure is disclosed on page 2. Also the use of the product in wheat flour, food fiber and soybean powder is shown on page 3. The amount of cyclodextrin and gamma-linolenic acid is shown at page 4. Although "reduced trans" is not mentioned in the reference, low trans products are well known in the art as being an inherent ingredient of natural fats (see Swern at cited page). Wheat and soybean flour are well known in the art to be inherent, common ingredients in starch-based foods.

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Claims 11, 12, 17 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is (571) 272-1403. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached on (571) 272-1398 or by dialing 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CAROLYN PADEN //-2-04
PRIMARY EXAMINER

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